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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,591	01/17/2006	Surachai Supattapone	DC0258US.NP	6069
26259	7590	07/18/2008	EXAMINER	
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			BABIC, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1637	
			NOTIFICATION DATE	
			07/18/2008	DELIVERY MODE
				ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/553,591	SUPATTAPONE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	CHRISTOPHER M. BABIC	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 April 2008.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) 2 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1 and 3 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>10/17/05; 3/13/06</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of group I, claims 1 and 3, in the reply filed on April 7, 2008 is acknowledged. The traversal is on the ground(s) that Saborio does not teach an isolated preparation of a ribonucleic acid molecule which enhances the amplification of PrP<sup>Sc</sup>. Thus, the ribonucleic acid molecule cannot be held to be anticipated by the teachings of Saborio. This is not found persuasive because claim 1 does not recite an isolated preparation of a ribonucleic acid molecule. Therefore, Applicant's arguments are not commensurate in scope with the claimed invention. Thus, the restriction requirement is still deemed proper and hereby made FINAL. As such, claim(s) 2 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.**

Claim 1 is directed to a naturally occurring composition of matter as demonstrated by Saborio et al. ("Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding" *Nature*. 2001 Jun 14;411(6839):810-3).

First, it is noted that the claimed invention recites the composition in "open", i.e. comprising language, which allows the inclusion of outside components. Furthermore, the ribonucleic acid molecule is not recited as "isolated" or "purified" with respect to its natural surroundings.

Saborio teaches a composition comprising: a ribonucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup> (fig. 2-3, healthy hamster brain homogenate necessarily contains nucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup>, polyadenylated hamster mRNA, for example). In its natural form, the ribonucleic nucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup> occurs in hamster brain tissue. Thus, the claimed invention, broadly interpreted, encompasses a naturally occurring life form, i.e. a hamster.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim(s) 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Saborio et al. ("Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding" Nature. 2001 Jun 14;411(6839):810-3).**

Saborio teaches in vitro amplification of PrP<sup>Sc</sup> (abstract; fig. 1, PMCA, for example). Specifically, Saborio teaches a composition comprising: a ribonucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup> (fig. 2-3, healthy hamster brain homogenate necessarily contains nucleic acid molecule that enhances the amplification of PrP<sup>Sc</sup>, i.e. Saborio teaches that the conformation of PrP<sup>C</sup> to PrP<sup>Sc</sup> is enhanced in the presence of healthy hamster brain homogenate, for example).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saborio et al. ("Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding" Nature. 2001 Jun 14;411(6839):810-3) in view of Stratagene ("Gene Characterization Kits" 1988).**

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach kits of reagents.

Stratagene catalog provides a supportive teaching that highlights a motivation to combine reagents into kit format (pg. 39, for example).

It would have been *prima facie* obvious to a skilled artisan at the time the invention was made to combine the reaction reagents as taught by Saborio into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused

chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (pg. 39, col. 1, for example).

### ***Conclusion***

#### **No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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